

reasonable expectation of success. Finally, the prior art reference ... must teach or suggest all the claim limitations.

In view of this standard, Applicants traverse the present rejection.

According to the Office, the sole reference in this case, Garner, discloses

nearly all that is recited in the claims since it teaches a process of extracting nicotine (corresponding to the claimed "reducing an amount of a constituent") from tobacco, wherein tobacco leaves containing approximately 10-25% by weight of water is placed into a filter-cloth bag and immersed in a liquefied (normally gaseous) hydrocarbon, such as propane (corresponding to the claimed "a hydrocarbon") at substantially room temperature (40-90 degrees F) and 3-30 pounds pressure per square inch -which obviously means that the extraction environment is below the critical point of the liquid hydrocarbon (and, hence, meets the "subcritical fluid" recitation). The tobacco-hydrocarbon mixture is left for several hours until a sufficient concentration of the extractives from the tobacco is obtained in the liquid, afterwhich said liquid is drawn off and directed to a tank, and the nicotine is separated, using any of a variety of methods, and used for various purposes. The liquid is then redirected back to the tobacco for further extractions (See entire document).

Claim 1

Claim 1 reads:

1. (Previously presented) A method of *reducing an amount of a constituent* in tobacco, said method comprising the steps of:
 - (a) providing a vessel containing said tobacco comprising said constituent;
 - (b) *contacting said tobacco with a subcritical fluid consisting of carbon dioxide or a hydrocarbon* wherein said amount of said constituent dissolves in said subcritical fluid; and
 - (c) removing said subcritical fluid from said vessel, thereby *reducing the amount of said constituent in said tobacco*.

Applicants note that Garner does not teach “reducing an amount of a constituent” or “contacting said tobacco with a subcritical fluid consisting of carbon dioxide or a hydrocarbon” as required by claim 1.

In connection with the phrase “reducing an amount of a constituent in said tobacco,” as set for in claim 1 step (c) and claim 5 step (d), Applicants’ specification (page 4, lines 7-8) clearly defines a “constituent” as “secondary alkaloids” and “polycyclic aromatic hydrocarbons (PAHs)” found in tobacco. Furthermore, Applicant’s specification (page 4, lines 10-13) defines a “secondary alkaloid” to mean “N-nitrosodimethylamine, N-nitrosodiethylamine, N-nitrosopyrrolidine, N-nitrosodiethanolamine, N-nitrosonornicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), N-nitrosoanatabine (NAT), or N-nitrosoanabasine (NAB),” wherein a primary alkaloid (e.g., nicotine) is defined (page 4, line 14) as “any alkaloid other than a secondary alkaloid” set forth above. A “polycyclic aromatic hydrocarbon” is defined in Applicants’ specification (page 4, lines 8-10) as anthracene, anthanthrene, benzo(a)pyrene, coronene, fluoranthene, fluorene, naphthalene, phenanthrene, pyrene, or perylene.

In contrast, the Garner reference is directed to extracting nicotine, a primary alkaloid, from tobacco. Primary alkaloids are not encompassed in Applicant’s definition of reducing an amount of a constituent in tobacco (i.e., secondary alkaloids and PAHs), nor are primary alkaloids claimed in the present inventions, and as such, Applicants

assert that the Garner reference does not render the presently claimed invention obvious under 35 U.S.C. § 103.

In addition, Garner fails to teach or suggest “contacting said tobacco with a subcritical fluid consisting of carbon dioxide or a hydrocarbon”. Garner makes no mention whatsoever of contacting tobacco with a subcritical fluid of carbon dioxide. Also, Garner, at best, teaches a mixture of anhydrous ammonia and a hydrocarbon. Garner’s mixture of anhydrous ammonia and a hydrocarbon fails to teach, suggest, or motivate one skilled in the art to employ contacting tobacco with a subcritical fluid *consisting* of a hydrocarbon. It is unreasonable to assume that the skilled worker when reading Garner would employ subcritical fluid hydrocarbon, when Garner specifically teaches a mixture of anhydrous ammonia and a hydrocarbon. The Office further provides no reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art reference in the manner claimed.

For all of the aforementioned reasons, the obviousness rejection as applied to claim 1 should be withdrawn.

Claims 2-4

Claims 2, 3, and 4 read:

2. (Previously presented) A method of *selectively reducing an amount of a secondary alkaloid relative to a primary alkaloid in tobacco*, said method comprising the steps of:

- (a) providing a vessel containing said tobacco comprising said secondary alkaloid and said primary alkaloid;
- (b) contacting said tobacco with a subcritical fluid wherein a greater amount of said secondary alkaloid relative to said primary alkaloid dissolves in said subcritical fluid; and
- (c) removing said subcritical fluid from said vessel, thereby *selectively reducing the amount of said secondary alkaloid relative to said primary alkaloid in said tobacco.*

3. (Previously presented) A method of *reducing an amount of a polycyclic aromatic hydrocarbon (PAH) in tobacco*, said method comprising the steps of:

- (a) providing a vessel containing said tobacco comprising said PAH;
- (b) contacting said tobacco with a subcritical fluid wherein said amount of said PAH dissolves in said subcritical fluid; and
- (c) removing said subcritical fluid from said vessel, thereby *reducing the amount of said PAH in said tobacco.*

4. (Previously presented) A method of *selectively reducing an amount of a PAH relative to a primary alkaloid in tobacco*, said method comprising the steps of:

- (a) providing a vessel containing said tobacco comprising said PAH and said primary alkaloid;
- (b) contacting said tobacco with a subcritical fluid wherein a greater amount of said PAH relative to said primary alkaloid dissolves in said subcritical fluid; and
- (c) removing said subcritical fluid from said vessel, thereby *selectively reducing the amount of said PAH relative to said primary alkaloid in said tobacco.*

As is discussed above, Garner extracts nicotine, a primary alkaloid, making no mention of removing “secondary alkaloids” relative to a “primary alkaloid.” Applicants submit that, in the present case, the Garner reference fails to provide a clear and particular suggestion, teaching, or motivation to arrive at the claimed invention. Indeed, under federal circuit case law, the evidence of a suggestion, teaching, or motivation “must be clear and particular.” *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617

(Fed. Cir. 1999), *abrogated on other grounds by In re Gartside*, 203 F.3d 1305, 53

U.S.P.Q.2d 1769 (Fed. Cir. 2000). Garner fails to meet this test.

With respect to claims 2-4, the Office states:

It follows that the same method that removes nicotine would also remove the other claimed constituents since the process can utilize liquid propane, and the extraction solvent, which is the same liquid used by Applicant which accomplishes the removal of the claimed constituents.

This conclusion appears to be based on an inadvertent mischaracterization of the reference. First, as stated above, nicotine, a primary alkaloid, is not a constituent for the purposes of the instant claims. In addition, nicotine is a distinct chemical entity from the specifically defined PAHs and secondary alkaloids of the present invention, and there is no evidence that a process that removes nicotine would necessarily result in a reduction of PAHs and/or secondary alkaloids. Moreover, the Office's conclusion that two methods that employ the same solvent yield the same result is rebutted by experimental data provided in the instant specification. For example, Table 3 (page 10) provides data on the selective reduction of secondary alkaloids compared to primary alkaloids, such as nicotine, in tobacco by treatment with subcritical propane. Table 4 (page 10) shows data on the selective reduction of PAHs in tobacco by treatment with subcritical propane.

Table 3.

Sample	Conditions (°C/psi)	pH	Mass of Propane: Mass of Tobacco	% Moisture Content	% Secondary Alkaloids Reduction	% Primary Alkaloids Reduction
1	20/ 1200	6	22	15	13	10
2	20/ 1200	6	22	60	58	3
3	20/ 1200	8	25	60	51	67

Table 4.

Sample	Conditions (°C/psi)	pH	Mass of Propane: Mass of Tobacco	% Moisture Content	% PAHs Reduction	% Primary Alkaloids Reduction
1	30/ 1000	6	24	16	77	14

Collectively, these data indicate that secondary alkaloids and PAHs may be extracted preferentially from tobacco compared to primary alkaloids, such as nicotine. In addition, the data also indicate that the conditions under which a particular extraction is performed affect what is extracted from the tobacco, compare samples 1-3 in Table 3. Thus, based on the experimental evidence, one cannot conclude that simply because the same solvent is employed in two methods, the same result will be achieved. Thus, there is no basis for the Office to conclude that Garner teaches or suggests the instant claims.

Claim 5

Claim 5 reads:

5. (Previously presented) A method of *reducing an amount of a constituent in tobacco*, said method comprising the steps of:

- (a) providing a system comprising a plurality of connected vessels containing said tobacco comprising said constituent;
- (b) contacting tobacco in a first vessel with a subcritical fluid wherein said amount of said constituent dissolves in said subcritical fluid;
- (c) removing said subcritical fluid from said first vessel; and
- (d) directing said subcritical fluid to a second vessel, thereby *reducing the amount of said constituent in said tobacco* in said first vessel.

As is discussed above, Garner fails to teach or suggest “reducing the amount of a constituent in tobacco” as presently claimed. Moreover, the Office in the present action has failed to explain the reasons one of ordinary skill in the art would have been motivated to select the Garner reference to render the claimed invention obvious. Indeed, the Office has not identified any motivation to choose the Garner reference or elements within this reference. Garner does not specifically address removal of constituents as claimed by Applicants. To the extent that Garner at all addresses extraction of tobacco, Garner addresses this subject through methods of extracting nicotine, a primary alkaloid. Garner also does not teach the choice of a particular subcritical fluid or combination of subcritical fluids as claimed. The Office provides no reasons that one of ordinary skill in this art, seeking to reduce the claimed constituents, would rely on Garner in a manner that would render the claimed invention obvious.

Claims 15 and 17

In connection with claims 15 and 17, the Office states:

while Garner may not disclose that citric acid or magnesium silicate is used for separating the constituents from the liquid hydrocarbon it does state that the extract can be treated with any suitable solvent **to remove the nicotine**, and other constituents, therefrom. And since either citric or magnesium based solutions are well-known in the use of liberating nicotine [from] solutions it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the claimed substances for this purpose.
(emphasis added).

As is stated above in connection with the rejection as applied to claims 1 and 5, nicotine is not a constituent for the purposes of the instant claims, and this basis of the obviousness rejection should therefore be withdrawn.

Claim 30

Finally, the Office, in connection with claim 30, which depends from any of claims 1-5, states:

while Garner may not specifically state that the tobacco has a pH of between 4-9, this is not deemed to patentably distinguish the claims from the reference since one having ordinary skill in the art would have arrived at the claimed pH, after routine experimentation, in order to find the optimal acidity under which to operate the process.

In response, Applicants reiterate each of their reasons found above as to why Garner fails to render claims 1-5 obvious.

Withdrawal of Finality

The Office has stated that the reason for making the Office action final is that “Applicant’s amendments necessitated the ... rejection.” Nothing in the previous amendments changed the scope in such a way as to make Garner applicable to the currently pending claims but not to the claims as originally filed. Thus, Applicants’ amendment did not necessitate the new grounds of rejection. The rejection over Garner could have and should have been made in the previous Office action in order to give Applicants a fair chance to consider and respond to the rejection. Applicants request that the finality of the Office action be withdrawn, and the arguments filed herewith be considered under 37 C.F.R. § 1.111.

If the Office disagrees with Applicants’ position on finality, the Office is requested to explain on the record how the amendments made in applicants’ previous reply necessitated the present rejection over Garner.

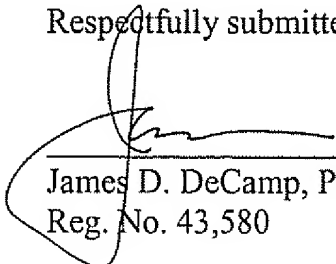
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for reply for two months, to and including September 25, 2006.

Please apply all charges and credits to Deposit Account No. 03-2095.

Respectfully submitted,

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